Remarks

This Amendment is in response to the Office Action dated **August 22, 2008.** Claims 1-14, 35-38 and 55 are pending in this application. The Office Action rejected claim 1 under 35 USC § 102 over Orth (US 5591197); rejected claims 1, 13, 35-37 and 55 under 35 USC § 102 over Mitsudou (US 7029492); rejected claims 1, 7-11, 13, 14, 35-38 and 55 under 35 USC § 102 over Bashiri (US 2003/0045923); rejected claims 7, 8 and 14 under 35 USC § 103 over Orth; rejected claims 2, 7-9 and 38 under 35 USC § 103 over Mitsudou; rejected claims 2 and 12 under 35 USC § 103 over Bashiri; rejected claims 3-6 and 10-12 under 35 USC § 103 over Mitsudou in view of Acosta (2004/0093061); and rejected claims 3-6 under 35 USC § 103 over Bashiri in view of Acosta.

By this Amendment, claims 1, 2, 4-6, 8, 10, 14 and 35-37 are amended, claim 3 is cancelled and new claims 56 and 57 are added. Claim 2 has been rewritten in independent form along with a minor clarifying amendment. Independent claims 1 and 35 have been amended, and dependent claims 4-6, 8, 10, 14, 36 and 37 have been amended in accordance with the amendments to the independent claims from which they depend. Applicants reserve the right to prosecute any cancelled subject matter in a subsequent patent application claiming priority to the immediate application. Reconsideration in view of the above amendments and the following remarks is requested.

Claim Rejections – 35 USC § 102

The Office Action rejected, under 35 USC § 102 , claim 1 over Orth; claims 1, 13, 35-37 and 55 over Mitsudou; and claims 1, 7-11, 13, 14, 35-38 and 55 over Bashiri. Although the rejections are traversed, claim 1 is amended in order to further prosecution of the application. The rejections are discussed below according to the applied references.

Orth – 35 USC § 102

The Office Action rejected claim 1 under 35 USC § 102 over Orth. The rejection is traversed because Orth does not teach a connector strut that disengages by electrolytic detachment; however, claim 1 has been amended to further prosecution of the application. The amendment renders the rejection moot.

Claim 1 recites "an electrical lead." Orth does not disclose or suggest an electrical lead. Therefore, Orth does not disclose or suggest each limitation of claim 1, and claim 1 is patentable over Orth under 35 USC § 102. Applicants request withdrawal of the rejection over Orth.

Mitsudou – 35 USC § 102

The Office Action rejected claims 1, 13, 35-37 and 55 under 35 USC § 102 over Mitsudou. These rejections are traversed because Mitsudou does not disclose or suggest a connector strut that disengages by electrolytic detachment.

Further with respect to claim 1, the amendment to claim 1 has rendered the rejection moot. Claim 1 recites "an electrical lead." Mitsudou does not disclose or suggest an electrical lead. Therefore, Mitsudou does not disclose or suggest each limitation of claim 1, and claim 1 is patentable over Mitsudou under 35 USC § 102. Claim 13 depends from claim 1 and is patentable over Mitsudou for at least the reasons discussed with respect to claim 1. Applicants request withdrawal of the rejection of claims 1 and 13 under 35 USC § 102 over Mitsudou.

With respect to claim 35, Mitsudou does not disclose or suggest that any "mass of the metal in the metal framework decreases upon disengagement of said disengagable connector strut," as recited in claim 35.

The rejection asserts that "upon breakage, it is inherent that material will break off the disengageble connector, thus it is inherent that the mass of the metal framework...will decrease upon disengagement." See Office Action at page 3. This assertion is traversed.

Mitsudou teaches that a weak connection portion located in the vicinity of the axial center of the stent can be broken by inserting an inflation balloon through the stent sidewall and inflating the balloon. See e.g. column 3, lines 53-61 and excerpt from Figure 18, provided below. Thus, Mitsudou teaches mechanical breakage of a weak connection resulting from applied mechanical force. Mitsudou does not teach that any mass is lost upon breakage of the weak connection portions, and the rejection attempts to rely on inherency.

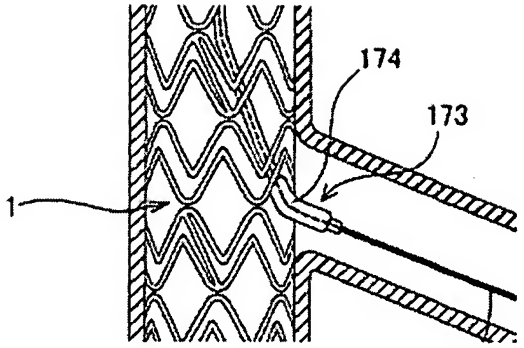

FIG. 18

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

A person of ordinary skill in the art would recognize that the weak connection portions of the Mitsudou stent are capable of the mechanical breakage without losing any mass. Further, person of ordinary skill in the art would recognize that breaking without any loss of material is preferable to the situation asserted by the rejection - wherein stray fragments might be left in a patient's vessel. Therefore, the Mitsudou stent does not necessarily lose mass upon breakage of the weak connection, and the rejection has not established inherency of the loss of mass limitations recited in claim 35.

The rejection further asserts "if the disengageble connectors were disengaged by electrolytic detachment, the connectors would corrode in order to break thus decreasing the mass." See Office Action at page 3.

Mitsudou does not disclose or suggest electrolytic detachment. A person of ordinary skill in the art would recognize that the stent, as taught by Mitsudou, is not capable of electrolytic detachment. Therefore, the assertion of electrolytic detachment is not relevant to the patentability analysis under 35 USC § 102.

Mitsudou does not disclose or suggest each limitation of claim 35, and claim 35 is patentable over Mitsudou under 35 USC § 102. Claims 36, 37 and 55 depend from claim 35 and are patentable over Mitsudou for at least the reasons discussed with respect to claim 35. Applicants request withdrawal of the rejection of claims 35-37 and 55 under 35 USC § 102 over Mitsudou.

Bashiri – 35 USC § 102

The Office Action rejected claims 1, 7-11, 13, 14, 35-38 and 55 under 35 USC § 102 over Bashiri.

Without forming an opinion as to the validity of the rejections, Applicants note that amendments to the independent claims have rendered the rejections moot. Independent claims 1 and 35 each recite first and second serpentine bands, wherein at least one permanent connector strut and a plurality of disengageble connector struts connect each valley of the first serpentine band to each peak of the second serpentine band. Bashiri does not disclose a stent having the claimed configuration.

Further, independent claim 1 recites "an electrical lead." Bashiri does not disclose or suggest an electrical lead.

With respect to claim 35, Bashiri does not disclose or suggest that any "mass of the metal in the metal framework decreases upon disengagement of said disengagable connector strut," as recited in claim 35.

The rejection asserts that "upon breakage, it is inherent that material will break off the disengageble connector, thus it is inherent that the mass of the metal framework...will decrease upon disengagement." See Office Action at page 5. This assertion is traversed.

Bashiri teaches that frangible restraining members break when a sufficient radially and/or axially outward force is applied to the stent. Bashiri teaches that the stent is desirably delivered on a balloon based delivery system and the frangible restraining members are broken upon expansion of the balloon or other application of force. See e.g. paragraph 0034. Thus, Bashiri teaches mechanical breakage of the frangible restraining members resulting from mechanical force. Bashiri does not teach that any mass is lost upon breakage of the frangible restraining members, and the rejection attempts to rely on inherency.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

A person of ordinary skill in the art would recognize that the frangible restraining

members of the Bashiri stent are capable of the mechanical breakage without losing any mass. Further, person of ordinary skill in the art would recognize that breaking without any loss of material is preferable to the situation asserted by the rejection. Therefore, the Bashiri stent will not necessarily lose mass upon breakage of the frangible restraining members, and the rejection has not established inherency of the loss of mass limitations recited in claim 35.

The rejection further asserts "if the disengageble connectors were disengaged by electrolytic detachment, the connectors would corrode in order to break thus decreasing the mass." See Office Action at page 5.

Bashiri does not disclose or suggest electrolytic detachment. A person of ordinary skill in the art would recognize that the stent, as taught by Bashiri, is not capable of electrolytic detachment. Therefore, the assertion of electrolytic detachment is not relevant to the patentability analysis under 35 USC § 102.

Bashiri does not disclose or suggest each limitation of independent claims 1 or 35, and these claims are patentable over Bashiri under 35 USC § 102. Each rejected dependent claim is patentable over Bashiri for at least the reasons discussed with respect to the independent claim from which it depends. Applicants request withdrawal of the rejections under 35 USC § 102 over Bashiri.

Claim Rejections – 35 USC § 103

The Office Action rejected, under 35 USC § 103, claims 7, 8 and 14 over Orth; claims 2, 7-9 and 38 over Mitsudou; claims 2 and 12 over Bashiri; claims 3-6 and 10-12 over Mitsudou in view of Acosta; and claims 3-6 over Bashiri in view of Acosta. These rejections are traversed, and are discussed below grouped according to the primary references.

Orth – 35 USC § 103

The Office Action rejected claims 7, 8 and 14 under 35 USC § 103 over Orth.

The amendment to claim 1 has rendered these rejections moot. Each claim rejected under 35 USC § 103 depends from claim 1. Claim 1 recites "an electrical lead." Orth does not disclose or suggest an electrical lead, and the rejection does not propose to modify Orth in a way that would add an electrical lead. Therefore, the applied reference does not teach every

limitation of the rejected claims, and the rejection does not propose a modification to Orth that would result in a device that meets the limitations of the rejected claims. Applicants request withdrawal of the rejections under 35 USC § 103 over Orth.

Mitsudou – 35 USC § 103

The Office Action rejected claims 2, 7-9 and 38 under 35 USC § 103 over Mitsudou. These rejections are traversed.

With respect to claim 2, the rejection does not establish any teaching of a stent formed from two materials, wherein one of the materials has a higher corrosion potential than the other. Although the rejection asserts that the claimed configuration would have been an obvious matter of design choice, the rejection does not provide any teaching that establishes the possibility of the claimed configuration. The rejection has not shown that the claimed configuration would have been a possible design choice. Therefore, the rejection has not established that each limitation of claim 2 exists in the prior art, and further has not identified any reasoning that would have prompted a person of skill in the art to make a stent according to claim 2.

With respect to claims 7-9, which depend from claim 1, the amendment to claim 1 has rendered the rejections moot. Mitsudou does not disclose or suggest an electrical lead as recited in claim 1, and the modifications proposed in the rejection would not result in a device that meets the limitations of claims 7-9.

With respect to claim 38, which depends from claim 35, Applicants have argued above that Mitsudou does not disclose or suggest that any "mass of the metal in the metal framework decreases upon disengagement of said disengagable connector strut," as recited in claim 35. See above section addressing the rejection of claim 35 over Mitsudou under 35 USC § 102 . The rejection of claim 38 proposes to modify Mitsudou by forming the stent of a self-expanding material. See Office Action at page 7. Even if the modification were performed, the resulting device would not meet the requirement that the mass of metal decreases upon disengagement of the disengagable connector strut. Therefore, the rejection has not satisfied each limitation recited in claim 38.

Applicants request withdrawal of the rejection of claims 2, 7-9 and 38 under 35

USC § 103 over Mitsudou.

Mitsudou and Acosta – 35 USC § 103

The Office Action rejected claims 3-6 and 10-12 under 35 USC § 103 over Mitsudou in view of Acosta. These rejections are traversed.

The rejection proposes to modify Mitsudou by adding an electrode in order to break the connectors. See Office Action at pages 8-9.

A person of ordinary skill in the art would not have made the modification proposed in the rejection because Mitsudou teaches a stent configured for specific breakage of a small portion of weak connectors. The specific weak connectors are broken by using a balloon to enlarge an opening in the sidewall, to allow stent implantation at a vessel branch/bifurcation. Electrolytic detachment is not a suitable alternative for the balloon/sidewall opening enlargement method taught by Mitsudou because electrolytic detachment cannot shape the stent framework in the same way as the balloon. Further, if the mechanical/balloon breakage method taught by Mitsudou is used, there is no reason to use an electrode as proposed in the rejection.

Mitsudou teaches a stent formed from a plurality of wavy annular members (e.g. 2b), which are connected by connection portions 4. See column 3, lines 48-53 and excerpt from Figure 4 provided below.

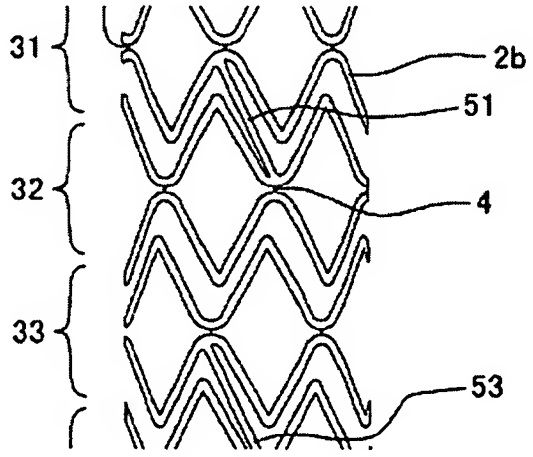

FIG. 4

Mitsudou teaches that some of the connection portions 4 located in the vicinity of the axial center of the stent are weakened, and can be broken by inserting an inflation balloon through the stent sidewall and inflating the balloon. See e.g. column 3, lines 53-61 and excerpt

from Figure 18, provided below.

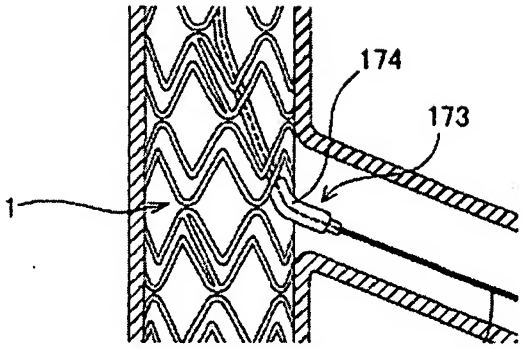

FIG. 18

As the balloon 174 is inflated, portions of the annular elements 2a, 2b in contact with the balloon 174 are dilated and the weak connector 4 oriented over the branch vessel is broken. This creates an enlarged opening that "reduces the possibility that blood flowing from the main blood vessel 170 to the branched blood vessel 172 is blocked and allows insertion of another balloon catheters, blood vessel dilation device, and stent into the branched blood vessel 172." See column 26, lines 26-51 and Figures 22 and 23, provided below.

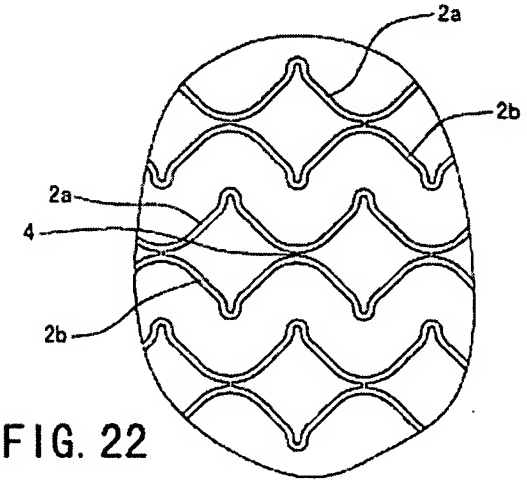

FIG. 22

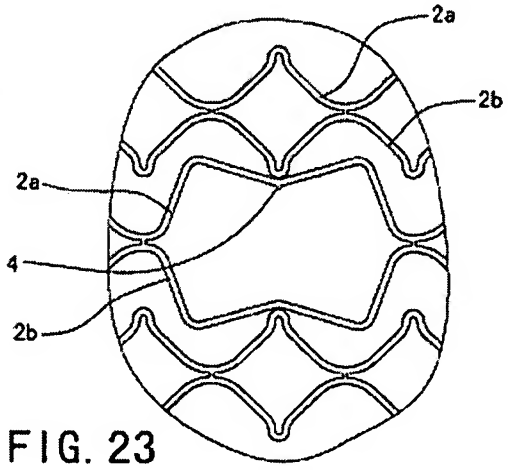

FIG. 23

A person of skill in the art would recognize that although very few connection portions 4 are broken in the Mitsudou method, the Mitsudou stent is provided with many weakened connection portions 4. This ensures that any connection portion(s) 4 that eventually become oriented over a branch vessel are weakened, and thus breakable. Although many or all of the connection portions 4 may be weakened, the connection portions 4 that are not broken during sidewall dilation still contribute to scaffolding strength and overall rigidity of the stent.

The rejection does not discuss the specifics of how an electrode would be added to the Mitsudou stent, or how the electrolytic disengagement could be controlled so that only connection portions 4 that become oriented over a branch vessel would be broken. A person of skill in the art would recognize that a general disengagement of all of the weak connection portions 4 by electrolytic detachment would not be desirable. Further, even if the stent could be arranged such that only connection portions 4 located over the branch vessel are electrolytically detached, mere detachment of those particular connection portions 4 would not provide an adequate side branch opening because the framework pattern of the annular members 2a, 2b would remain as shown in Figure 22. Thus, the annular members 2a, 2b would impede flow to the branch vessel unless the stent sidewall is otherwise dilated. Therefore, providing an electrode to the Mitsudou stent is not a suitable alternative to the sidewall balloon dilation method taught by Mitsudou.

If the stent sidewall is dilated using a balloon as taught by Mitsudou, there is no reason to detach any connection portions 4 electrolytically. Thus, when using the balloon, there is no need to modify the Mitsudou stent by adding an electrode, as proposed in the rejection.

In light of these reasons, a person of ordinary skill in the art having common sense would not perform the modification to Mitsudou proposed in the rejection. Therefore, the rejection does not establish a *prima facie* case of unpatentability against the rejected claims. Applicants request withdrawal of the rejection of claims 3-6 and 10-12 under 35 USC § 103 over Mitsudou in view of Acosta.

Bashiri – 35 USC § 103

The Office Action rejected claims 2 and 12 under 35 USC § 103 over Bashiri; and rejected claims 3-6 under 35 USC § 103 over Bashiri in view of Acosta.

Without forming an opinion as to the validity of the rejections, Applicants note that amendments to the independent claims have rendered the rejections moot. Independent claims 1 and 35 each recite first and second serpentine bands, wherein at least one permanent connector strut and a plurality of disengageble connector struts connect each valley of the first serpentine band to each peak of the second serpentine band. Bashiri does not disclose a stent having the claimed configuration, and the modifications to Bashiri proposed in the rejections

would not result in a stent that meets the limitations of the pending claims. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 103 applying Bashiri.

Conclusion

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1, 2, 4-14, 35-38 and 55-57 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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